REMARKS

To expedite prosecution, claim 1 has been amended. Support for this amendment can be found throughout the specification, in particular on page 14, lines 15-19. Claims 1-15, 17, 29-31, and 36-48 are now pending. Reconsideration is respectfully requested in view of the following remarks.

Claim Rejections Under 35 U.S.C. 103:

The Examiner rejected claims 1-15, 17, 29-31, and 36-48 as amended under 35 U.S.C. 103(a) as being unpatentable Nyce (5,527,789) in view of Ansel et al. (Pharmaceutical Dosage Forms and Drug Delivery System, page 454-455).

Nyce only discloses a "nasal" formulation and not an "inhalable or respirable formulation." Further, the Examiner asserts that Ansel discloses particles of size 0.5 μm to 5 μm and Remington's discloses particles of size 0.5 μm to 0.7 μm. As claim 1 has been amended to cover particles of about 6 μm to about 100 μm in size. Particles of the claimed range pass into the lungs and are not retained in the nasal cavity. Applicant believes that the rejection is moot as Nyce in combination with Ansel and Remington do not teach all the limitations of the amended claims.

The Examiner has also asserted that the "particle size limitation would be inherently present in the nasal inhalation compositions of the prior art ...." The Ansel and Remington references do not teach particles of greater than 6 μm for inhalation and also, the amended claims provide that the particles would move into the lungs and not be retained in the nasal cavity.

Overall, Applicant maintains that the composition of the amended claim 1 is not known based on Nyce as Nyce does not disclose specific particle sizes that would be suitable as provided by the present invention. Further, there is no expectation of success based on the cited references that the claim combination of claim 1 would be a suitable formulation with out significant side effects. In fact, the respirable and/or inhalabe formulations are developed for agents that are desired to have systemic effects, such as insulin. However, as seen from Dr. Robinsons's declaration, a inhalable formulation of DHEA not only has the desired local effects in the lungs, it also does not have significant side-effects of systemic assimilation in the body. There is no indication of an expectation of such a success in any of the cited references.

III. Double Patenting:

The Examiner has rejected claims 1-15, 17, 29-31, and 36-48 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 159 of copending Application No. 10/072,010. Applicant has cancelled claim 159 and hence believes that this rejection is now moot.

CONCLUSION

In light of the remarks set forth above, Applicants believe that they are entitled to a letters patent. Applicants respectfully solicit the Examiner to expedite the prosecution of this patent application to issuance. Should the Examiner have any question, the Examiner is encouraged to telephone the undersigned.

Respectfully submitted,

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